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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,414	07/19/2001	Frank L. Graham	AdVec10CA	7286

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

15

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/909,414

Applicant(s)

GRAHAM ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-13 are pending in this application. Receipt is acknowledged of the preliminary amendment, received 1/10/02 (Paper No. 4).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9, 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite, since the phrase "contacting or introducing into a cell" is unclear. It is assumed that the phrase is intended to mean contacting a cell or introducing into a cell.

Claim 9 is vague and indefinite, since the phrase "said first plasmid and said second plasmid" lack antecedent basis.

Claim 11 is vague and indefinite, since part (c) appears incomplete starting with the phrase "when said".

Claim 12 recites improper Markush language as the word "and" should be between the last two members of the group.

Claim 13 is vague and indefinite, since it recites limitations in part (a) (ii) (A) which are not encompassed by claim 7, on which it is dependent. Presumably, this should be rewritten as an independent claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-13 rejected under 35 U.S.C. 102(b) as being anticipated by Kaleko (WO 97/25446).

Kaleko teaches a method for making an infectious adenovirus which comprises contacting a cell with, or introducing into a cell, a first nucleic acid sequence, containing adenovirus sequences insufficient to encode an infectious adenovirus, comprising at least one site-specific recombinase recognition target site which is recognized by a site-specific recombinase, (see page 5, line 32 – page 6, line 5), and a second nucleic acid sequence encoding adenovirus sequences which, in the absence of adenoviral replication factors provided in trans or intermolecular recombination with said first nucleic acid sequence, are insufficient to encode an infectious adenovirus, and

Art Unit: 1636

additionally comprising a recombinase recognition target site, whereby said first and said second nucleic acid sequences, in combination and following site specific intermolecular recombination, result in production of an infectious adenovirus (see page 6, line 6-31). The site-specific recombinase which recognizes said site-specific recombinase recognition target sites may be expressed by a cell into which said first and said second nucleic acids are introduced such as 293 cells, on a third nucleic acid (see page 7, lines 16-21), or on the first or second nucleic acid (page 10, lines 13-15). The reference discloses an embodiment in which the first nucleic acid is a plasmid which contains adenovirus sequences insufficient to encode an infectious, replicable or package able adenovirus, comprising the 5' ITR, packaging signal, a heterologous DNA and a recombinase target 3' of the heterologous DNA (page 8 lines 3-28). The first nucleic acid may be deleted for adenovirus protein encoding genes (page 11-13). The recombinase recognition site may be lox, and the recombinase may be Cre (pages 12-13). The reference discloses kits comprising said nucleic acids.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaleko (WO 97/25446) (cited above), in view of Bett et al. (Proc. Natl. Acad. Sci. USA 91:8802-8806 (1994)).

Kaleko's teachings are set forth above. The difference between Kaleko and the instant claim is that the first nucleic acid includes a bacterial origin and antibiotic resistance gene for selection in bacteria.

Bett et al. disclose vectors containing a bacterial origin, an antibiotic resistance gene for selection in bacteria, and Ad5 DNA sequences (see abstract), and discloses their wide applications for the construction of Ad vectors for use as recombinant viral vaccines and for gene therapy transfer vectors (see page 8806, second column line 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vectors, kits, and methods disclosed by Kaleko to include a bacterial origin and an antibiotic resistance gene for selection in bacteria in the first nucleic acid, as taught by Bett et al., since Bett et al. state that adenovirus vectors containing said bacterial origin and resistance gene may be widely applicable for systems used in the construction of adenovirus vectors, and since Kaleko teach that the first nucleic acid is preferably a plasmid.


One would have been motivated to modify the nucleic acid of Kaleko by the desire to easily manipulate the nucleic acid using a bacterial host, said host being well known in the art for ease of cultivation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv  
August 6, 2003

  
REMY YUCEL, PH.D.  
SUPERVISORY PATENT EXAMINER  
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